Docket No.: 425802000200
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Amy E. BAKER

Application No.: 09/557,187 Confirmation No.: 7012

Filed: April 21, 2000 Art Unit: 1617

For: SALICYLIC ACID ACNE SPRAY FORMULATIONS AND METHODS FOR TREATING ACNE WITH SAME Examiner: G. Mitchell

APPELLANT'S BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This brief is in furtherance of the Notice of Appeal, filed on October 28, 2004.

The fees required under §1.17(f) and any required petition for extension of time for filing this brief and fees therefor, are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains items under the following headings as required by 37 C.F.R. §1.192 and M.P.E.P. §1206:

I.	Real Party In Interest
II	Related Appeals and Interferences
III.	Status of Claims
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I. REAL PARTY IN INTEREST

The real party in interest for this appeal is:

Nature's Cure

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences that will directly affect or be directly affected by this appeal nor are there any other appeals or interferences that will have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in the Application

There are 18 claims pending in the application.

B. Status of Claims

Claims canceled: 3, 6, 12, 14
Claims withdrawn from consideration but not canceled: none
Claims pending: 1, 2, 4, 5, 7-11, 13, and 15-22
Claims allowed: none
Claims rejected: 1, 2, 4, 5, 7-11, 13, and 15-22

C. Claims On Appeal

The claims on appeal are claims 1, 2, 4, 5, 7-11, 13, and 15-22

IV. STATUS OF AMENDMENTS

No amendments have been submitted subsequent to the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The single independent claim in the application on appeal (Claim 1) is directed to a fine mist pump spray containing no propellant and adapted only for administration to non-facial body skin to

treat acne or acneform conditions thereon, the fine mist spray comprising a solution of salicylic acid, wherein the salicylic acid constitutes from about 0.01% to about 20% by weight of the solution and the pH of the solution is above about 5, whereby any nasal irritation or coughing caused by the fine mist spray is thereby reduced. In addition, the application also provides an article of manufacture for treating acne comprising the fine mist pump spray of claim 1, as well as methods of treating acne comprising administering a fine mist pump spray of claim 1 to non-facial skin afflicted with acne or an acneform condition.

The salicylic acid is present in the solution of from about 0.01% to about 20% by weight, or from about 0.5% to about 2% by weight. Specification, page 5, lines 9-14.

The solution containing salicylic acid may comprise a solvent system including water and a volatile solvent. Specification, page 4, lines 9-13. The volatile solvent may be alcohol, such as denatured ethyl alcohol. Specification, page 5, lines 14-19.

The spray will typically be used on non-facial body skin, e.g., back, arms, neck, and chest. Consumers frequently want to treat the afflicted skin area and then clothe themselves quickly. Thus, the invention spray is a fine mist spray that can be focused onto a small target skin area and dries quickly. Specification, page 6, lines 6-9. Furthermore, irritation and coughing in the user population can be significantly lessened by increasing the pH of the spray. Specification, page 6, lines 9-18, and page 11, lines 15-27. In particular, the pH may range from about 5 to about 7.2. Specification, page 7, lines 4-7.

The fine mist sprays of this invention may be dispensed from pump spray dispensers. Specification, page 7, line 13-22. The dispenser may be a 360 degree fine mist spray pump spray dispenser. Specification, page 8, line 12-13. The spray may comprise liquid particles of size from about 10 to about 150 micrometers. Specification, page 3, lines 16-18, and page 10, lines 10-24. The fine mist pump spray dispenser may dispense about 50 to 500 microliters of the solution per actuation. Specification, page 8, lines 7-9.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1) Claims 1, 2, 4, 5, 7-11, 13 and 15-22 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

2) Claims 1, 2, 4, 5, 7-11, 13 and 15-20 stand rejected under 35 U.S.C. §103(a) as unpatentable over Kozak (DE 003127590 A1) in view of U.S. Patent No. 5,976,521 to Briggs et al. ("Briggs") and U.S. Patent No. 4,322,020 to Stone ("Stone").
3) Claims 9 and 18 stand rejected under 35 U.S.C. §103(a) as unpatentable over Kozak in view of Briggs and Stone and further in view of U.S. Pat. No. 5,612,324 to Guang Lin et al. ("Guang Lin").
4) Claims 21 and 22 stand rejected under 35 U.S.C. §103(a) as unpatentable over Kozak in view of Briggs and Stone and further in view of U.S. Pat. No. 5,759,559 to Fitzjarrell ("Fitzjarrell").
5) Claim 19 stands rejected under 35 U.S.C. §103(a) as unpatentable over Kozak in view of Briggs and Stone and further in view of Sciarra (Remington: Practice of Science and Pharmacy).

VII. ARGUMENT

A. The 35 U.S.C. §112, Second Paragraph Rejection of Claims 1, 2, 4, 5, 7-11, 13 and 15-22 should be Reversed

Claims 1, 2, 4, 5, 7-11, 13 and 15-22 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. In support of the rejection, the Examiner has stated:

> "The term 'above about' in line 4 of claims 1 and 11 renders the claims vague and indefinite. It is not clear what pH is within the claimed range of 'above about' 5 (4 or 5.5). The remaining claims are rejected as depending on [in]definite base claims." (Office Action of December 22, 2003, page 3.)

The Examiner has not properly applied 35 U.S.C. §112. The test for definiteness under 35 U.S.C. §112, second paragraph is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ.2D 1081, 1088 (Fed. Cir. 1986). The *Manual of Patent Examination Procedure* (eighth) ("*MPEP*") §2173.02 (2004) cautions the Examiner not to reject a claim as indefinite merely when the Examiner feels that "more suitable language or modes of expression are available," but only when the recited language does not meet a minimum threshold of "reasonable" clarity. The phrase "above about 5" is not indefinite because this phrase would be clear to one of skill in the art reading the specification.

1. One of Skill in the Art would Understand what is Meant by "above about 5" in Light of the Specification

The phrase "above about" a given pH would be clear to one of skill in the art because it is discussed in the specification. Page 8-9 of the specification includes a section devoted to describing considerations for selecting the pH of the spray containing salicylic acid. In particular, the specification contemplates a range of pHs, including pHs "above about" a given pH. For example, the specification states:

> "In order to lessen the likelihood of causing nasal/throat irritation and coughing, it is preferable that the spray *have a pH above about 4.5*, usually about 4.5 to about 7.5. More preferable, the pH may range from about 5 to about 7.2. Even more preferably, the pH is substantially neutral, i.e., from about 6.9 to about 7.2." Specification, page 9, lines 4-7, emphasis added.

Thus, the specification describes a pH for a solution of salicylic acid that is *above about* a given pH level. One of skill in the art would understand what is meant by the recitation of a pH "above about 5" in claims 1 and 11 in view of this description. If the claims, read in light of the specification, reasonably apprise those skilled in the art of the scope of the invention, then 35 U.S.C. §112 is satisfied. *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1378, 55 USPQ.2D 1279, 1282 (Fed. Cir. 2000). Thus, the phrase "above about 5" meets the test for definiteness under the second paragraph of 35 U.S.C. §112.

2. The Phrase "above about 5" is Reasonably Clear on its Face

The recitation of "above about 5" meets the "reasonably clear" threshold for definiteness under §112, second paragraph. *MPEP* §2173.02. One of skill in the art would understand what is meant by "above about 5," and would therefore understand the scope of the recited term, because the phrase "above about 5" is reasonably clear on its face. As the Applicant remarked in the Amendment in Response to the Non-Final Office Action of December 22, 2004:

> "Applicant notes that the term "about" has consistently been held by the courts to be clear and definite, because one having ordinary skill in the art would know how to detect infringement. See, e.g., *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)...[T]he term "about" has been repeatedly used throughout claims in application after application, in order to help minimize the risk of an applicant being rigidly bound by a fixed number. Indeed, not allowing the term "about" to be used to indicate some slight variability about a number, would severely restrict the scope of the claims. Here, the pH is above 'about 5.' One having ordinary skill in the art would know that they could not

> avoid infringement by simply changing the pH to 5.1. Similarly, one having ordinary skill in the art reading the claim would know that they could not avoid infringement by simply changing the pH to 4.9. Indeed, the specification is clear on this matter..." (Response to the Non-Final Office Action dated April 22, 2004, page 5-6.)

The mere use of the term "about" does not render the phrase "above about 5" indefinite. Furthermore, the phrase "above about 5" adequately serves the notice function required by 35 U.S.C. §112, second paragraph, by providing clear warning to others what constitutes infringement of the patent. *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ.2D 1190, 1195 (Fed. Cir. 1993).

The Examiner argues that the phrase "above about 5" is indefinite because it is amenable to two different interpretations. However, the Examiner's argument is untenable. The threshold for determining if a claim term is indefinite is "reasonable" clarity. In other words, does the Applicant's claim language recite with reasonable clarity what is claimed? *MPEP* §2173.05. The Examiner argues that the phrase "above about 5" renders the claims indefinite because there are two different interpretations, and therefore one skilled in the art would not understand the scope of the invention. However, the examiner relies on an unreasonable alternative interpretation of the phrase "above about" to make this indefiniteness argument. According to the Final Office Action of July 28, 2004:

> "The combination of the terms 'above' and 'about' render the claim indefinite, however, for the reasons described in the previous Office Action [Office Action of December 22, 2003] and specifically because it is not clear what pH is within the claimed range of 'above about' 5. The phrase could be interpreted to mean *above 5, but only slightly above 5*, or it could be interpreted as simply being greater than any value equal to about 5." (Final Office Action of July 28, 2004, emphasis added.)

The Examiner's suggestion that the phrase "above about 5" also means "above 5, but only slightly above 5," is not reasonable. In English, a preposition commonly modifies the clause it immediately precedes. The American Heritage Book of English Usage: A Practical and Authoritative Guide to Contemporary English (1996). In the phrase, "above about 5," recited in claims 1 and 11, the reasonable object of the preposition "about" is 5, and the reasonable object of the preposition "above" is "about 5." Therefore, the phrase "above about 5" is an appropriate phrase to express the range of pHs consistent with the specification. The Examiner is insisting on an unreasonable and unlikely interpretation of the phrase "above about." The Examiner's

interpretation of "above 5, but only slightly above 5" instead describes a phrase such as "about above 5." This is not a phrase used in the claims or specification. In contrast, the phrase "above about 5" would be reasonably clear to one of skill in the art, as required by 35 U.S.C. §112, second paragraph. *MPEP* §2173.02.

3. The Objection under 35 U.S.C. §112, Second Paragraph, Cannot Stand

Claim 1 and 11 and the claims that depend from those claims are reasonably clear because one having ordinary skill in the art would recognize what is meant by a pH "above about 5." The phrase "above about" is clear on its face, and is also as described in the specification. Thus, Applicant has met the requirement of 35 U.S.C. §112, second paragraph.

Reversal of the rejections under 35 U.S.C. §112, second paragraph, is requested.

B. The 35 U.S.C. §103(a) Rejections of Claims 1, 2, 4, 5, 7-11, 13 and 15-20 over Kozak in view of Briggs and Stone should be Reversed

Under 35 U.S.C. §103(a), the Examiner bears the burden of establishing a *prima facie* case of obviousness. *See, e.g., In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ.2d 1955, 1956 (Fed. Cir. 1993); and *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ.2d 1443, 1444 (Fed. Cir. 1992). The establishment of a *prima facie* case requires the Examiner to demonstrate three elements, and failure to demonstrate any one of the three elements compels the conclusion that the *prima facie* case has not been established. *MPEP* § 2143. The three elements are: (1) every limitation of the claimed invention is taught or suggested in the cited reference or references when combined (*In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1970)); (2) there must be a suggestion or motivation to combine the references, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art (*In re Fritch*, 972 F.2d 1260, 23 USPQ.2d 1780 (Fed. Cir. 1992), and *In re Lee*, 277 F.3d 1338, 1339, 61 USPQ.2d 1430, 1431 (Fed. Cir. 2002)); and (3) there must have been a reasonable expectation of success on the part of one of ordinary skill in the art, at the time the invention was made, in carrying out the invention suggested by the combined references (*In re Oetiker*, id.; *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed.Cir. 1986), *Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 47 USPQ.2D 1027 (Fed. Cir. 1998)).

In response to the Examiner's initial presentation, the Applicant may present evidence that the Examiner has not met the burden of presenting a *prima facie* case by showing that the Examiner has failed to meet any one of the three requirements. The Applicant may also present evidence, such as unexpected success or teaching away in the art, to rebut a *prima facie* case of obviousness. The Examiner must respond to the evidence produced by the Applicant by reconsidering any initial obviousness determination in view of the entire record. The Office Action should clearly communicate the Examiner's findings and conclusions, articulating how the conclusions are supported by the findings. The findings should clearly articulate which portions of the reference support any rejection. Explicit findings on motivation or suggestion to select the claimed invention should also be articulated in order to support a 35 U.S.C. §103 ground of rejection. Conclusory statements of similarity or motivation, without an articulated rationale or evidentiary support, do not constitute sufficient factual findings. *MPEP* §2144.08, III.

In the present case, the Examiner has not established even one of the three required elements of a *prima facie* case of obviousness. Furthermore, the Applicant has presented evidence, virtually unanswered by the Examiner, which rebuts the establishment of a *prima facie* case. Hence, the Examiner has failed to show that a combination of the cited references would render the claimed invention unpatentable.

1. Summary of the Rejection of Claims 1, 2, 4, 5, 7-11, 13 and 15-20

Claims 1, 2, 4, 5, 7-11, 13 and 15-20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kozak in view of Briggs and Stone. In support of the rejection, the Office Action states:

> "Kozak teaches that it is well known in the art to formulate a topical composition comprising salicylic acid and additional active ingredients into sprayable form. See abstract. The reference teaches using 0.02-6 g of salicylic acid and resorcinol. The method of treating acne with the prior art composition is taught...
>
> Kozak fails to teach the pH of the composition and using 'fine mist pump spray'. The reference also fails to teach aqueous alcoholic solvent.
>
> Briggs teaches an anti-acne composition comprising salicylic acid. See abstract. To deliver salicylic acid in aqueous solution but without the salicylic cid precipitating out of solution, the reference teaches that the salicylic acid is dissolved in aqueous/alcoholic

solution. See col. 1, line 63 – col. 2, line 37... Briggs further teaches that the preferred pH of the final aqueous/alcoholic anti-acne active solution is preferably in the range of about 1-7. See col. 3, lines 37-47... Ethyl alcohol is preferred and used in the illustrated formulation for the aqueous phase, which contains salicylic acid. See col. 3, lines 1-47; col. 11, lines 35-40... From about 0.1 to about 10% of salicylic acid is used. See col. 2, lines 61-67; instant claim 10.

Briggs fails to teach fine mist pump spray.

Stone teaches an invertible fine mist pump sprayer which is useful to dispense cosmetic or pharmaceutical compositions. See col. 1, line 9 – col. 2, line 65. The reference teaches that pump sprays are preferred over aerosols because of the clogging problem in the aerosol valves and environmental concerns. See col. 1, lines 22-35. In Example 1, the reference describes a topical anesthetic solution spray having an average particle size of approximately 200 microns when the viscosity of the solution is 37 cps. at 20°C.

While the particle size does not expressly meet the limitation of instant claim 2, the reference teaches 'the particle size of the spray will vary with the rheology of the liquid being sprayed as well as with the orifice size.' See col. 5, lines 44 – 49. It is further disclosed, 'the lower the viscosity of the liquid and the smaller the orifice size, the smaller the particle size obtained.' The reference even teaches that for applying cosmetics, spray particle size of 50-500 microns is desirable. See col. 1, lines 18-21. Thus it would have been obvious to a routineer to produces the spraying the desired range for topical formulations with the expectation that a low viscous solution would produce smaller spray particles.

Given the teaching of formulating salicylic acid topical composition in the form of spray, one having ordinary skill in the art at the time the invention was made to have looked to the prior arts such as Stone because of the expectation of successfully producing a spray with the desired spray effects (fine spray particles, usability from various angles, etc.) while eliminating the problems with aerosol value and environmental concerns." (Office Action of December 22, 2003, pages 4-5.)

2. The Examiner Failed to Make a Prima Facie case of Obviousness.

The Examiner has failed to forth a *prima facie* case of obviousness under §103, because the Examiner has not established any of the elements required. If even one of the elements required to set forth a *prima facie* case of obviousness is not shown, then the obviousness rejection should be withdrawn. First, Kozak, Briggs and Stone (individually or in combination) do not teach or suggest every limitation of the claimed invention. Second, there is no suggestion or motivation to combine

Kozak, Briggs and Stone. Finally, there would not have been a reasonable expectation of success in carrying out the invention suggested by combining Kozak, Briggs and Stone.

a. Kozak, Briggs and Stone do not teach or suggest every limitation

Independent claim 1 recites limitations that are neither taught nor suggested by Kozak, Briggs or Stone, or the combination of Kozak, Briggs and Stone: independent claim 1 recites a fine mist pump spray (1) "adapted only for administration to non-facial body skin," (2) comprising a solution of salicylic acid where "the pH of the solution is above about 5," (3) whereby "any nasal irritation or coughing caused by the fine mist spray is thereby reduced."

i. Kozak, Briggs and Stone do not Teach or Suggest a Fine Mist Pump Spray "Adapted Only for Administration to Non-Facial Body Skin"

None of Kozak, Briggs, or Stone teach or suggest the limitation that the fine mist pump spray is "adapted only for administration to non-facial body skin," as recited in claim 1 and incorporated into claims 2, 4, 5, 7-11, 13 and 15-20. Kozak describes an anti-acne composition, Briggs describes an anti-acne cosmetic, and Stone describes an invertable pump sprayer. Furthermore, the combination of Kozak, Briggs and Stone does not teach or suggest a fine mist pump spray "adapted only for administration to non-facial body skin."

The Examiner has not argued that Kozak, Briggs or Stone teach or suggest a fine mist pump spray that meets the "adapted only for administration to non-facial body skin" limitation of independent claim 1. Instead, the Examiner has maintained that the phrase "adapted only for administration to non-facial body skin" is merely "a preamble reciting intended use of the composition," and has ignored it, giving the term no patentable weight. (Office Action of December 22, 2003, page 3.) However, the phrase "adapted only for administration to non-facial body skin" recited in the preamble of claim 1 should be given full patentable weight as a limitation because it is a structural limitation and is intended to be limiting by the applicant.

(a). The Recitation of "Adapted Only for Administration to Non-Facial Body Skin" in the Preamble is Limiting

The Examiner is incorrect by flatly asserting that a limitation in the preamble is not entitled to any weight. Limitations in the preamble of a claim must be considered for patentability when they are necessary to give meaning to the claim and properly define the invention. *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 221 USPQ 669 (Fed. Cir. 1984). The effect preamble language should be given can be resolved only on "review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works v. Sumitomo Electric U.S.A.*, 868 F.2d 1251, 9 USPQ.2d 1962 (Fed. Cir. 1989); *see also Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1572-73, 40 USPQ2d 1481, 1488 (Fed. Cir. 1996) ("Whether a preamble stating the purpose and context of the invention constitutes a limitation of the claimed process is determined on the facts of each case in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history.") Thus, the test to determine if a preamble is limiting requires looking at the entire record to see what the inventor actually invented, and what was intended to be encompassed by the claim. Furthermore, as a general rule, structural limitations in a preamble should always be given effect as claim limitations. *Corning Glass Works,* id.

In this case, it is clear that (1) the inventor intended the preamble phrase "adapted only for administration to non-facial body skin" to be limiting; (2) the preamble limitation "adapted only for administration to non-facial body skin" implicates structural limitations; and (3) there are differences between devices adapted for administration to *only* non-facial body skin, and devices adapted for administration to both facial and non-facial skin, or only facial skin. Thus, the recitation of the preamble is a limitation that is neither taught nor suggested by Kozak, Briggs, Stone, or the combination of Kozak, Briggs and Stone.

(b). The Applicant Intended the Preamble to be Limiting

It is clearly the Applicant's intention that the limitation in the preamble be encompassed by the claims. The Applicant has made it clear during the course of prosecution that the scope of her invention encompasses a pump spray that is adapted for application to non-facial body skin for the treatment of non-facial acne. The specification describes this in detail. For example, see page 6 of

the specification ("the spray will typically be used on non-facial body skin"). The inventor and her attorneys have also discussed this with the Examiner on multiple occasions. Finally, the prosecution history contains numerous references that the Applicant desires to limit her invention to a pump spray that is adapted for application to non-facial body skin. (For example, the Amendment Under 37 C.F.R. §1.111 in Response to Non-Final Office action of December 22, 2004, page 8 ("the spray being adapted for application to non-facial body skin for the treatment of non-facial acne is a part of her [Applicant's] invention"); and the submitted packaging for applicant's commercial spray (submitted with the March 10, 2003 Amendment) ("[d]o not spray directly on or near your face").) Thus, the preamble was both intended to be limiting, and was relied on as limiting by the Applicant, demonstrating that it is a claim limitation for the purpose of patentablity. *See Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 62 USPQ.2D 1781 (Fed. Cir. 2002) ("[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention."); *see generally Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375, 58 USPQ.2D 1508, 1513 (Fed. Cir. 2001).

(c). The Recitation of "Adapted Only for Administration to Non-Facial Body Skin" in the Preamble is a Structural Limitation

Furthermore, the preamble should be limiting because it contains structural limitations. *Corning Glass Works*, id. The recitation of "adapted only for administration to non-facial body skin" in the preamble also provides a reference point for the interpretation of all other claim limitations. A preamble that modifies the interpretation of other claim limitations is a structural limitation. *Perkin-Elmer Corp.*, id; *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 48 USPQ.2D 1225 (Fed. Cir. 1998), ("[T]he preamble described a 'reference point' that provided guidance in understanding and construing the claim"). All of the other claim limitations are viewed in light of the limitation that the mist pump spray is adapted only for administration to non-facial body skin. Thus, the salicylic acid composition (ranging from about 0.01% to about 20% by weight), the pH (chosen from the range defined by "about above 5"), and the reduction of nasal irritation or coughing are limitations of independent claim 1 that are further modified by the preamble's requirement that the mist pump spray is adapted only for administration to non-facial

body skin. For example, the specification describes a concentration of salicylic acid and a pH of the spray that does not result in substantial nasal irritation or coughing when applied only to non-facial body skin. Example 2, page 11. However, this same concentration of salicylic acid and pH may result nasal irritation and coughing when applied to facial skin. Thus, the "adapted only for administration to non-facial body skin" is a structural limitation necessary to give meaning to the claims and properly define the invention.

(d). Devices Adapted for Administration to Only Non-Facial Body Skin Are Not the Same as Devices for Administration to Facial Skin

There are necessarily structural differences between devices adapted for administration to *only* non-facial body skin, and devices adapted for administration to both facial and non-facial skin (or just facial skin). The specification describes ways in which fine mist pump sprays for non-facial use must be adapted in ways that distinguish them from pump sprays for facial use. For example, the specification describes how fine mist pump sprays adapted only for administration to non-facial body skin must consider drying time on the body. *See* specification, page 6 ("[since] consumers frequently want to treat the afflicted skin areas and then clothe themselves quickly, the invention spray is a fine mist spray that can be focused onto a small target skin area and dries quickly"). Other adaptations specific to fine mist pump sprays only for administration to non-facial body skin may include spray amount, nozzle shape, and spray pattern. Thus, the preamble invokes structural limitations. Structural limitations should be given effect as claim limitations. *Corning Glass Works,* Id.

(e). The Recitation of "Adapted Only for Administration to Non-Facial Body Skin" in the Preamble is a Limitation that is Not Met

The Examiner's assertion that the phrase "adapted only for administration to non-facial body skin" is a mere preamble describing an intended use is incorrect. The Examiner incorrectly argues that it "does not provide any additional limitation to the composition or characteristic of the spray." (Final Office Action of July 28, 2004, page 3.) This assertion is wrong because the fine mist pump is further limited by being adapted *only* for administration to non-facial body skin. Furthermore, the Applicant clearly intended that this limitation be effective. There are differences between fine mist pumps that are adapted for only administration to non-facial body skin and fine mist pumps adapted

for facial skin. Thus, the recitation of "adapted only for administration to non-facial body skin" in the preamble is a limitation for the purposes of patentability. The art made of record completely fails to address this limitation. Kozak, Briggs and Stone are not adapted for "non-facial use" as recited in claim 1 and incorporated into dependent claims 2, 4, 5, 7-11, 13 and 15-20. Thus, the Examiner has failed to establish a *prima facie* case of obviousness, and the 35 U.S.C. §103(a) rejection of claims 1, 2, 4, 5, 7-11, 13 and 15-20 should not stand for at least this reason.

ii. Kozak, Briggs and Stone do not Teach or Suggest Solutions of Salicylic Acid having a pH above about 5

Furthermore, the Examiner has failed to make the requisite *prima facie* case of obviousness because the combination of Kozak, Briggs and Stone do not teach or suggest a solution of salicylic acid having a pH above about 5, as required by the claims.

The Examiner relies upon Briggs to assert that the prior art teaches a salicylic acid solution having a pH above about 5. According to the Office Action of December 22, 2003, "Briggs further teaches that the preferred pH of the final aqueous/alcoholic anti-acne active solution is preferably in the range of about 1-7. See col. 3, lines 37-47." (Office Action of December 22, 2003, page 4.) The Examiner has misread Briggs. Briggs does not teach that the pH of a solution of *salicylic acid* will be in the range from about 1 to 7; instead Briggs teaches that the pH of a solution including *any of the contemplated anti-acne actives* will be in the range from about 1 to 7. Briggs goes on to teach that for *each* anti-acne active, including salicylic acid, the pH of the solution will be less than about 1 + the pK_a of the anti-active ingredient. One of skill in the art, reading Briggs, would understand that Briggs teaches a solution of salicylic acid having a pH less than about 4 (applying the commonly accepted pK_a for salicylic acid). Thus, Briggs does not teach a solution of salicylic acid having a pH that is above about 5, as required by independent claim 1.

(a). Briggs teaches that the pH of the anti-active agent depends on the pK_a of the agent

Briggs teaches cosmetic compositions comprising one or more of a list of possible anti-acne agents (referred to as "anti-acne actives"). Only one of the contemplated anti-acne agents is salicylic acid. For example, Briggs teaches that, "[s]uitable anti-acne actives for use herein *include* salicylic acid, retinoic acid, azelaic acid, lactic acid, glycolic acid, pyruvic acid, flavonoids, and

derivatives and salts thereof, and mixtures thereof." Briggs, col. 2, lines 57-60, emphasis added. Briggs further teaches that the pH of the aqueous/alcoholic solution containing the selected anti-acne agent is less than about 1 plus the pK_a of the agent. According to the specification:

> "The final aqueous/alcoholic anti-acne active solution preferably has a pH at ambient temperature (25°C.) of less than about pK_a +1, where pK_a is the logarithmic acidity constant for the fully protonated anti-acne active. In preferred embodiments, the pH of the final solution is less than about pK_a." Briggs, col. 3, lines 7-12.

Thus, for any anti-active agent, the pH range is dependent on the pK_a value of the agent. The pK_a value of a given compound is a constant at a given temperature that is the inverse natural log of the dissociation constant for that compound. Stephen Zumdahl, "Chemistry" 567 (1986). Thus, each of the anti-acne agents described by Briggs will have an associated pK_a, and therefore each anti-acne agent will have an associated pH range of "less than about pK_a + 1."

(b). The Examiner has misinterpreted Briggs

The Examiner recites line 41-43 in col. 3 of Briggs to support the assertion that Briggs teaches a solution of salicylic acid having a pH between 1 and 7. Brigg's specification reads: "[t]he pH of the final aqueous/alcoholic anti-acne active solution is preferably in the range of from about 1 to about 7." Briggs, col.3, lines 41-43. The Examiner has read this line out of its proper context. Read in the context of the specification, it is clear that Briggs is not describing a range of pHs specific to salicylic acid. Instead, Briggs is describing a pH range encompassing *any* appropriate "anti acne active" *including* the pH range of salicylic acid and all other appropriate anti-acne agents.

It is clear from Briggs that for individual anti-acne agents, an appropriate range of pHs is based on the pK_a. Brigg's discussion of pH is generic to any anti-acne agent, and does not specifically discuss salicylic acid. Furthermore, the four paragraphs immediately preceding the statement recited by the Examiner (Briggs, col. 3, lines 12-40) explicitly describe a general method of determining pK_a in order to determine the pH. One of skill in the art, following these teachings, would come up with a pH range "less than about pK_a + 1" for any acceptable anti-acne active. All of these pH ranges together describe the "range" of pHs (from 1 to about 7) described in lines 41-43 in col. 3 of Briggs.

The pH range for a solution of salicylic acid as taught by Briggs does not overlap with the range of "above about 5" as recited by independent claim 1.

(c). Briggs Teaches a pH Range for a Solution of Salicylic Acid of Less Than the Claimed Range

The pH range of a solution of salicylic acid taught by Briggs is less than about 1 + the pK_a of salicylic acid. Briggs does not describe a pK_a for salicylic acid. However, the pK_a of salicylic acid is widely accepted to be less than 3. *See, e.g.,* Popova, Pancheva1, and Uzunova, "Salicylic Acid: Properties," *Bulg. J. Plantphysiol.*, 23(1–2), 85–93, 86 (1997) (the pK_a of salicylic acid is 2.98 at 25°C); Chatton, Besseghir, and Roch-Ramel, "Salicylic acid permeability properties of the rabbit cortical collecting duct," *Am. J. Physiol.*, 259(4 Pt 2), 613-8 (1990) (the pK_a of salicylic acid is 3); Takagi, Taki, Sakane, Nadai, Sezaki, Oku and Yamashita, "A New Interpretation of Salicylic Acid Transport across the Lipid Bilayer: Implications of pH-Dependent but not Carrier-Mediated Absorption from the Gastrointestinal Tract ," *Pharmacol. and Experimental Therap.*, 285(3), 1175-1180 (1998) (the pK_a of salicylic acid is 3.0).

(d). The pH Limitation in Claim 1 of "above about 5" is not met

Briggs does not meet the limitation recited in independent claim 1 that the pH of the solution of salicylic acid is "above about 5." Furthermore, neither Kozak nor Stone individually (or in combination) teach or suggest this limitation. Thus, for at least this reason, the Examiner has failed to make a *prima facie* case of obviousness, since the combination of Kozak, Briggs and Stone can not meet this limitation. Since independent claim 1 (and claims 2, 4, 5, 7-11, 13 and 15-20 that depend from claim 1) require that the pH of the salicylic acid solution is "above about 5," the §103(a) rejection of the claims over Kozak, Briggs and Stone should be withdrawn.

iii. Kozak, Briggs and Stone do not Teach or Suggest Solutions of Salicylic Acid having a pH of above about 5 where "Any Nasal Irritation or Coughing Caused by the Fine Mist Spray is Thereby Reduced"

The Examiner has also failed to make the requisite *prima facie* case of obviousness because the combination of Kozak, Briggs and Stone do not teach or suggest a solution of salicylic acid

having a pH above about 5 where "any nasal irritation or coughing caused by the fine mist spray is thereby reduced," as required by claims 1, 2, 4, 5, 7-11, 13 and 15-20.

The Examiner has not argued that Kozak, Briggs or Stone teach or suggest the limitation that the solution of salicylic acid has a pH above about 5 where "any nasal irritation or coughing caused by the fine mist spray is thereby reduced." Instead, the Examiner has maintained that the recited phrase "any nasal irritation or coughing caused by the fine mist spray is thereby reduced" is merely "an inherent property of salicylic acid contacting fine mist spray with a pH above 5." (Office Action of December 22, 2003, page 4.)

The Examiner is incorrect in completely ignoring, or considering inherent, this limitation. The Examiner failed to establish that this limitation is an inherent property. In particular, the Examiner has not provided the requisite adequate basis in fact and/or technical reasoning to support a determination that the allegedly inherent characteristic necessarily flows from the prior art.

(a). The Examiner has not shown that Kozak, Briggs or Stone inherently teach a fine mist spray where "Any Nasal Irritation or Coughing Caused by the Fine Mist Spray is Thereby Reduced"

A claimed feature is inherent only if it is *necessarily* present in a prior art device. *In re Robertson*, 169 F.3d 743, 49 USPQ.2d 1949 (Fed. Cir. 1999); *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 51 USPQ.2D 1943 (Fed. Cir. 1999); *Mehl/Biophile International Corp. v. Milgraum*, 192 F.3d 1362, 52 USPQ.2D 1303 (Fed. Cir. 1999). An Examiner relying on the theory of inherency must provide a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ.2D 1461, 1464 (Bd. Pat. App. & Inter., 1990). In the instant case, the Examiner has not provided evidence or reasoning sufficient to establish inherency. The only extrinsic evidence offered in support of the allegation of inherency is a reference to U.S. Patent No. 4,287,190 to Boettcher et al. ("Boettcher"). According to the Final Office Action of July 28, 2004:

> "...as the pH of Briggs et al. increased from 1 to 7, irritation caused by the salicylic acid would decease. About two decades prior to Applicant's application, Boettcher et al. disclosed that it was advantageous to increase the pH of Salicylic acid to prevent irritation (column 2, lines 42-46). Accordingly, given the length of time that it has been known that

> an increase in pH will prevent irritation, it is the Examiner's position that the missing component (i.e. "whereby any nasal irritation or coughing caused by the fine mist spray is thereby reduced") would be recognized by one of ordinary skill in the art as an inherent property of salicylic acid spray with an increased pH, the declaration by Dr. Maibach, notwithstanding." (Final Office Action of July 28, 2004, page 4.)

Thus, the Examiner is arguing that Boettcher et al. shows that it was well known in the art that increasing the pH decreases irritation caused by salicylic acid. However, the Examiner is mischaracterizing Boettcher. In particular, Boettcher does not teach or demonstrate that *nasal irritation* is decreased by increasing the pH of salicylic acid. The only support for the Examiner's assertion that it was well-known is a single line in Boettcher that reads: "[o]ptimally the composition may also contain a buffer for increasing the pH to prevent irritation by the salicylic acid; such buffers may include, for example, sodium acetate." Boettcher, col. 2, lines 42-46. It is clear from the specification that the "irritation" referred to by Boettcher is skin irritation, since Boettcher describes applying the compounds by incorporating them into an ointment or cream ("The compositions are particularly suitable for topical application to animals to be treated and therefore may be in the form of a gel, an ointment, a paste, a cream or a lotion." Boettcher, col. 3, lines 42-47). Boettcher does not mention nasal irritation. It is well known by those skilled in the art that skin irritation is quite different from nasal irritation and coughing. *See, e.g.*, Pan, Molhave, and Kjaergaard, "Effects on eyes and nose in humans after experimental exposure to airborne office dust," *Indoor Air*, 10(4), 237-45 (2000).

There is no reason to believe that the mediation of skin irritation mentioned in passing by Boettcher (which may simply be the result of neutralizing the acidity of the salicylic acid), is even related to the reduction in nasal irritation or coughing recited by the Applicant. Thus, Boettcher is not a basis in fact and/or technical reasoning sufficient to support a determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

Furthermore, the Examiner's naked assertion that the limitation of, "any nasal irritation or coughing caused by the fine mist spray is thereby reduced" is inherent because it is "necessarily present in a composition comprising salicylic acid that has [a] pH above about 5" is insufficient to establish inherency. Such statements are particularly insufficient in view of the Declaration by Dr. Howard Maibach, an expert in the field of Dermatology, who stated that "it was not obvious to me,

nor do I believe it would have been obvious [to] others, that...increasing the pH of the formulation—as Ms. Baker ultimately did—would significantly reduce these symptoms." (The Declaration of Howard Maibach, M.D. ¶ 5(b) submitted with Applicant's response to Office Action of June 4, 2003.)

Thus, the Examiner cannot rely on the theory of inherency.

(b). The Limitation of "Any Nasal Irritation or Coughing Caused by the Fine Mist Spray is Thereby Reduced" is Not Met

None of Kozak, Briggs or Stone, or any combination thereof teach or suggest a solution of salicylic acid having a pH above about 5 where "any nasal irritation or coughing caused by the fine mist spray is thereby reduced," as required by claims 1, 2, 4, 5, 7-11, 13 and 15-20. For at least this reason, the Examiner has failed to make a *prima facie* case of obviousness, since the combination of Kozak, Briggs and Stone can not meet this limitation. Thus, the §103(a) rejection of the claims over Kozak, Briggs and Stone should be withdrawn.

b. There is No Motivation to Combine Kozak, Briggs and Stone

Establishing a motivation to combine references sufficient to make a *prima facie* case of obviousness may be made using the explicit or implicit teaching of the prior art, the nature of the problem to be solved, and the knowledge of persons of ordinary skill in the art. *In re Lee,* 277 F.3d 1338, 61 USPQ.2d 1430 (Fed. Cir. 2002); *In re Rouffet,* 149 F.3d 1350, 1357, 47 USPQ.2d 1453, 1457 (Fed. Cir. 1998). However, the Examiner must provide some clear and particular showing of the motivation to combine; mere conclusory statements are not sufficient. *In re Lee,*id; *Teleflex, Inc. v. Ficosa North American Corp.*, 299 F.3d 1313, 63 USPQ.2d 1374 (Fed. Cir. 2002).

In the instant case, the Examiner has not provided *any* motivation to combine Kozak, Briggs and Stone. Kozak was asserted as prior art by the Examiner for the first time in the Office Action of December 22, 2003, because the Examiner believed it "shows a stronger teaching" than Fitzjarrell. (Office Action of December 22, 2003, page 8.) In fact, Fitzjarrell taught away from the use of salicylic acid, and therefore away from combination with Stone and Briggs. (*See* Amendment Under 37 C.F.R. §1.111 in Response to Non-Final Office Action of June 4, 2003, pages 2-3; and Amendment Under 37 C.F.R. §1.111 in Response to Non-Final Office Action of September 10,

2002, page 7; and section VIII, D, below.) However, after replacing Fitzjarrell with Kozak, the Examiner provided no further motivation to combine Kozak, Stone and Briggs.

Instead, the Examiner has relied on conclusory statements that combining the references would have been obvious to one of skill in the art at the time the invention was made, because of an expectation of success. (*See* Final Office Action of July 22, 2004, page 5; and Office Action of December 22, 2003, page 3-4.) Such conclusory statements are inadequate. *MPEP* §2144.08, III. Furthermore, the fact that one of skill in the art *can* successfully combine references is not a sufficient showing of motivation to combine references. *In re Lee,* id; *In re Mills,* 916 F.2d 680, 16 USPQ.2d 1430 (Fed. Cir. 1990).

Neither Kozak nor Briggs explicitly suggest any motivation or benefit from combining with each other, or with Stone. In particular, there is no motivation to combine Kozak with Briggs and with Stone to achieve a fine mist pump spray containing no propellant and adapted only for administration to non-facial body skin to treat acne or acneform conditions thereon, the fine mist spray comprising a solution of salicylic acid, wherein the salicylic acid constitutes from about 0.01% to about 20% by weight of the solution and the pH of the solution is above about 5, whereby any nasal irritation or coughing caused by the fine mist spray is thereby reduced. Since the Exmaminer has failed to show any motivation to combine Kozak, Briggs and Stone, the examiner has failed to make a *prima facie* case of obviousness for at least this reason. Thus, the §103(a) rejection of claims 1, 2, 4, 5, 7-11, 13 and 15-20 should be withdrawn.

c. There is No Reasonable Expectation of Success if Kozak, Briggs and Stone are Combined

A "reasonable expectation of success" requires that one of ordinary skill in the art would expect to be able to successfully combine the references. *Velander v. Garner*, 348 F.3d 1359, 68 USPQ.2D 1769 (Fed. Cir. 2003). In the instant case, the combination of Kozak, Briggs and Stone does not have a reasonable expectation of success, at least because the topical anti-acne solutions of Kozak are not compatible with the anti-acne emulsion taught by Briggs.

Briggs teaches a cosmetic having anti-acne properties. Further, Briggs teaches that this cosmetic is a "multiple phase, water-in-oil" emulsion. Briggs col. 2, lines 53-54. This emulsion is

appropriate for "creams, lotions or gels" useful as makeup (e.g. foundation and liquid concealer). Briggs, col.10, lines 39-42. It is "essential" to Briggs that the emulsion have at least two aqueous phases that are kept separate by a colescence inhibitor. Briggs, col 3, lines 48-53. One of skill in the art would not expect a multi-phase oil-and-water composition such as that taught by Briggs to be successfully delivered as a fine mist pump spray, as required by the claims, because Briggs teaches multi-phase solutions that are too viscous.

The combination of Briggs's multiple-phase emulsion with Kozak and Stone would not be expected to succeed. One of skill in the art, reading Briggs's disclosure, would not expect that the "thick" (high viscosity) solutions that Brigg's teaches would be capable of forming a fine mist, particularly using the pump spray taught by Stone. For example, Briggs describes multiple-phase emulsions that are made suitable for use as a cosmetic by agents that substantially thicken the multiple-phase emulsion. For example, Briggs describes incorporating complexing agents (Briggs, col. 4, lines 10-40), silicones (col. 4, line 53 to col. 6, line 58), humectants (Briggs, col. 6, line 60 to col. 7, line 13), and powdered materials (e.g. pigments). Stone's pump sprayer is described as compatible with "liquid materials having viscosities as high as 100 cps." Stone, Abstract. However, 100 cps is still relatively "thin," or non-viscous. By comparison, vegetable oil has a viscosity higher than 100 cps at room temperature. One of skill in the art would not expect that the "creams, lotions or gels" taught by Briggs would form a "fine mist" using the Stone teaching. It is more likely that the spray pump taught by Stone would clog if used to apply a material as taught by Kozak in light of Briggs.

Since one of skill in the art would not reasonably believe that the combination of Kozak, Briggs and Stone would succeed, the Examiner has failed to make a *prima facie* case of obviousness. The rejection of claims 1, 2, 4, 5, 7-11, 13 and 15-20 should be withdrawn for at least this reason.

3. The 35 US §103(a) Rejection over Kozak, Briggs and Stone Cannot Stand

The 35 U.S.C. §103(a) rejection of claims 1, 2, 4, 5, 7-11, 13 and 15-20 over Kozak, Briggs and Stone should be withdrawn because the examiner has failed to make a *prima facie* case of obviousness. In particular, this rejection should be withdrawn because the Examiner has failed to

show that all of the claim limitations are present in the combination of Kozak, Briggs, and Stone. In addition, the rejection should be withdrawn because the Examiner has failed to show any motivation to combine Kozak, Briggs and Stone. Furthermore, the rejection should be withdrawn because one skilled in the art would have no reasonable expectation of success by combining Kozak, Briggs and Stone.

C. The 35 U.S.C. §103(a) Rejections of Claims 9 and 18 over Kozak in view of Briggs, Stone and Guang Lin should be Reversed

Claims 9 and 18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kozak in view of Briggs and Stone and further in view of Guang Lin. In support of the rejection, the Office Action states: "Guang Lin teaches anti-acne composition comprising salicylic acid in aqueous/ethanol carrier. See Examples. SD (specifically denatured) alcohol is used in the formulation. See instant claims 9 and 18." (Office Action of December 22, 2003, page 6.)

As described above, under 35 U.S.C. §103(a), the Examiner bears the burden of establishing a *prima facie* case of obviousness. Failure to demonstrate any one of the elements of the *prima facie* case of obviousness compels the conclusion that the *prima facie* case has not been established, and therefore the claims are not obvious in light of the cited references. *MPEP* § 2143. The Examiner has failed to demonstrate a *prima facie* case of obviousness for the Applicant's claims over Kozak, Briggs and Stone. Described in section VII, B, above, and incorporated herein as if set forth in full detail. Furthermore, the addition of Guang Lin does not cure any of the defects of Kozak, Briggs and Stone with respect to making a *prima facie* case of obviousness. Therefore the rejection of claims 9 and 18 under 35 U.S.C. §103(a) should be withdrawn.

1. Guang Lin dose not cure the defects of Kozak, Briggs and Stone.

Guang Lin cannot supplement the combination of Kozak, Briggs and Stone so that the claimed invention is obvious in light of this combination. Guang Lin describes an anti-acne composition including salicylic acid and pantothenic acid. In particular, Guang Lin does not teach or suggest a fine mist pump spray "adapted only for administration to non-facial body skin." Further, Guang Lin does not teach or suggest solutions of salicylic acid having a pH of above about 5 whereby "any nasal irritation or coughing caused by the fine mist spray is thereby reduced."

Thus, the Examiner has not made a *prima facie* case of obviousness, for at least the reason that the combination of Kozak, Briggs, Stone and Guang Lin do not teach or suggest all of the limitations of claim 9 or claim 18.

Futhermore, the Examiner has failed to provide any motivation to combine Guang Lin with Kozak, Briggs and Stone. The Examiner offers only a conclusory statement that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the aqueous alcohol vehicle for salicylic acid in the combined references by substituting the ethanol with conventionally used denatured ethanol as motivated by Guang Lin because of an expectation of successfully producing similar salicylic acid aqueous solution." The fact that one of skill in the art *can* successfully combine references is not a sufficient showing of motivation to combine references. *In re Mills,* id; *MPEP* § 2143.01.

2. The 35 US §103(a) Rejection over Kozak, Briggs, Stone and Guang Lin Cannot Stand

The 35 U.S.C. §103(a) rejection of claims 9 and 18 over Kozak, Briggs, Stone and Guang Lin should be withdrawn because the examiner has failed to make a *prima facie* case of obviousness.

D. The 35 U.S.C. §103(a) Rejections of Claims 21 and 22 over Kozak in view of Briggs, Stone and Fitzjarrell should be Reversed

Claims 21 and 22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kozak in view of Briggs and Stone and further in view of Fitzjarrell. In support of the rejection, the Office Action states: "Fitzjarrell teaches that salicylic acid is used and well-known anti-acne agent used for mild acne. See col. 1, lines 17-28; col. 2, lines 28-36." (Office Action of December 22, 2003, page 6.)

The Examiner has failed to demonstrate a *prima facie* case of obviousness of the Applicant's claims over Kozak, Briggs and Stone. *See* section VII, B, above. Furthermore, the addition of Fitzjarrell does not cure any of the defects of Kozak, Briggs and Stone with respect to making a *prima facie* case of obviousness. Therefore the rejection of claims 9 and 18 under 35 U.S.C. §103(a) should be withdrawn.

Fitzjarrell teaches a method for treating acne, particularly acne on the "O or elliptically shaped area of the face that includes the nose and chin" that combines a topical spray of niacinamide with an oral supplement comprising lysine, selenium, zinc and chromium. Fitzjarrell, col. 1, lines 38-40 and col. 2, lines 8-11. The addition of Fitzjarrell to Kozak, Briggs and Stone does not cure any of the deficiencies in the examiner's prima facie case for obviousness as described above in section VIII, B. Furthermore, Fitzjarrell teaches away from using salicylic acid to treat acne or acneform conditions.

1. Fitzjarrell Teaches Away from Using Salicylic Acid to Treat Acne

The Applicant reiterates the argument that Fitzjarrell, far from teaching one skilled in the art to use salicylic acid to treat acne, teaches *away* from using salicylic acid. In fact, Fitzjarrell mentions salicylic acid only once, in the background section of the patent. Fitzjarrell discusses salicylic acid only to point out that a combination of an oral supplement and topical niacinamide spray, as described in Fitzjarrell, should be used instead of salicylic acid and other treatments:

> "Mild acne can be treated with diet changes, careful washing and nonprescription lotions containing benzoyl peroxide, topical creams containing salicylic acid, or other medications. Vitamin A palmitate may be applied topically for the treatment of acne and other skin disorders as described by Lerner in U.S. Pat. Nos. 5,556,887 and 5,520,919. Severe acne may be treated with tetracycline, 13-cis-retinoic acid and other prescription drugs. The skin may be treated with acid or freezing in some cases to make the skin peel. These treatments are often unsuccessful and may have significant side effects. Often, at best, these treatments reduce the intensity or frequency of acne outbreaks." Fitzjarrell, col. 1, lines 25-37.

Thus, Fitzjarrell specifically and deliberately teaches away from using salicylic acid to treat acne, because it is "often unsuccessful and may have significant side effects." Fitzjarrell, col. 1, line 34-35. One of skill in the art, relying upon Fitzjarrell, would be *discouraged* from using salicylic acid to treat acne, and would instead look to Fitzjarrell's oral supplement and topical niacinamide spray. *In re Gurley*, 27 F.3d 551, 553, 31 USPQ.2D 1130, 1132 (Fed. Cir. 1994) ("[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant").

It is well settled that a *prima facie* case of obviousness may be rebutted by a showing that the prior art teaches away from the invention. *In re Peterson*, 315 F.3d 1325, 1331, 65 USPQ.2d 1379, 1383 (Fed. Cir. 2003) ("[A]n applicant may rebut a *prima facie* case of obviousness by showing that the prior art teaches away from the claimed invention in any material respect."); *Winner International Royalty Corp. v. Wang*, 202 F.3d 1340, 53 USPQ2d 1580 (Fed. Cir. 2000); *Tec Air, Inc. v. Denso Manufacturing Michigan Inc.,* 192 F.3d 1353, 52 USPQ2d 1294 (Fed. Cir. 1999).

The Examiner ignores the context of Fitzjarrells's statement regarding the use of salicylic acid to treat acne. In the Final Office Action of July 22, 2004, the Examiner states: "despite the side effects of and varying degrees of effectiveness, it is Examiner's position that Fitzjarrell does in fact teach the use of salicylic acid for the treatment of acne." (Final Office Action of July 22, 2004, page 5.) Thus, the Examiner is completely ignoring the fact that Fitzjarrell's description of salicylic acid in the background section teaches against using salicylic acid to treat acne in favor of the described combination of topical nicinamide spray and oral supplement.

Since Fitzjarrell teaches away from the using salicylic acid as an acne treatment, and therefore teaches away from any combination with Kozak, Briggs, and Stone, the Examiner has failed to make a *prima facie* case of obviousness for at least this reason.

2. The 35 US §103(a) Rejection over Kozak, Briggs, Stone and Fitzjarrell Cannot Stand

The examiner has failed to make a *prima facie* case of obviousness: the combination of Kozak, Briggs, Stone and Fitzjarrell does not contain all of the limitations of claims 21 or 22. In addition, Fitzjarrell teaches away from the use of Kozak, Briggs and Stone so there is no motivation to combine these references. Without a *prima facie* case of obviousness, the 35 U.S.C. §103(a) rejection of claims 21 and 22 over Kozak, Briggs, Stone and Fitzjarrell should be withdrawn.

E. The 35 U.S.C. §103(a) Rejections of Claim 19 over Kozak in view of Briggs, Stone and Sciarra should be Reversed

Claim 19 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Kozak in view of Briggs and Stone and further in view of Sciarra. In support of the rejection, the Office Action

states: "Sciarra teaches that topical aerosols have been used for preparations for the treatment of acne. See . 1676, 1st par... The reference further teaches that for a typical metered-dose aerosol delivery system for pharmaceuticals, the size of the chamber can be modified so that about 25-150 μL of the solution can be delivered per actuation, which meets claim 19." (Office Action of December 22, 2003, page 7.)

Claim 19 incorporates into its body the limitations of claim 1. The rejection of claim 1 based on Kozak, Briggs and Stone is discussed above in section VIII, B and these arguments are incorporated here as if set forth in detail. The examiner has failed to make a *prima facie* case of obviousness over claim 1 using Kozak, Briggs, and Stone. Furthermore, Sciarra cannot cure this deficiency, since Sciarra merely teaches the general use of aerosol devices for administering cosmetics and pharmaceuticals. Accordingly, the rejection of claim 18 over Kozka, Briggs, Stone and Sciarra should be withdrawn.

F. Conclusion

The various rejections provided in the Final Office Action are without legal basis and are without factual support. Appellants request reversal of each of the rejections.

VIII. CLAIMS APPENDIX

A copy of the claims involved in the present appeal is attached hereto.

IX. EVIDENCE APPENDIX

No additional evidence is entered or relied on in this appeal.

X. RELATED PROCEEDINGS APPENDIX

The Applicant is not aware of any related proceedings.

Dated: December 16, 2004

Respectfully submitted,

By 

Rick Shoop
Registration No.: 45,763
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304
(650) 813-5804

CLAIMS APPENDIX

Claims Involved in the Appeal of Application Serial No. 09/557,187

1. A fine mist pump spray containing no propellant and adapted only for administration to non-facial body skin to treat acne or acneform conditions thereon, the fine mist spray comprising a solution of salicylic acid, wherein the salicylic acid constitutes from about 0.01% to about 20% by weight of the solution and the pH of the solution is above about 5, whereby any nasal irritation or coughing caused by the fine mist spray is thereby reduced.

2. The spray of claim 1 wherein the spray comprises liquid particles of a size of from about 10 to about 150 micrometers.

3. (Canceled)

4. The spray of claim 3 wherein the pH is from about 5 to about 7.5.

5. The spray of claim 3 wherein the pH is from about 6.9 to about 7.2.

6. (Canceled)

7. The spray of claim 1 wherein the solution comprises a solvent system comprising water and a volatile solvent.

8. The spray of claim 7 wherein the volatile solvent is an alcohol.

9. The spray of claim 8 wherein the alcohol is denatured ethyl alcohol.

10. The spray of claim 1 wherein the salicylic acid constitutes about 0.5% to 2% by weight of the solution.

11. An article of manufacture for producing the fine mist spray of claim 1 comprising a solution of salicylic acid wherein the salicylic acid constitutes about 0.01% to 20% by weight of the solution and no propellant contained within a fine mist pump spray dispenser, and wherein the solution has a pH above about 5, and whereby any nasal irritation or coughing caused by the fine mist spray is thereby reduced.

12. (Canceled)

13. The article of claim 11 wherein the fine mist spray pump dispenser is a 360 degree fine mist spray pump spray dispenser.

14. (Canceled)

15. The article of claim 14 wherein the pH is in the range of about 5 to about 7.2.

16. The article of claim 11 wherein the solution comprises a solvent system comprising water and a volatile solvent.

17. The article of claim 16 wherein the solvent is an alcohol.

18. The article of claim 17 wherein the alcohol is denatured ethyl alcohol.

19. The article of claim 11 wherein the dispenser dispenses about 50 to 500 microliters of the solution per actuation.

20. A method for treating acne or acneform conditions on non-facial skin of a human comprising administering an effective amount of the fine mist spray of claim 1 to the afflicted skin of said human.

21. The spray of claim 1 wherein the sole active anti-acne ingredient(s) in the solution is salicylic acid.

22. The article of claim 11 wherein the sole active anti-acne ingredient(s) in the solution is salicylic acid.